

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF NORTH CAROLINA
DURHAM DIVISION

AMY BRYANT, MD,)
)
Plaintiff,)
v.)
)
JOSHUA H. STEIN, in his official)
capacity as Attorney General for the)
State of North Carolina, et al.,) Case No. 1:23-cv-00077
Defendants,)
) **ANSWER TO FIRST**
and) **AMENDED COMPLAINT**
)
TIMOTHY K. MOORE and)
PHILIP E. BERGER,)
)
Defendant-Intervenors.)
)

NOW COME Defendants, Michaux R. Kilpatrick, Christine M. Khandelwal, Devdutta G. Sangvai, John W. Rusher, William M. Brawley, W. Howard Hall, Sharona Y. Johnson, Joshua D. Malcolm, Miguel A. Pineiro, Melinda H. Privette, Anuradha Roa-Patel, Robert Rich, Jr., each in their official capacity, by and through the undersigned counsel and hereby answer Plaintiff's First Amended Complaint as follows:

ANSWER TO FIRST AMENDED COMPLAINT

1. Defendants admit, on information and belief, that the U.S. Food and Drug Administration ("FDA") issued Risk Evaluation and Mitigation Strategies ("REMS") for the FDA-approved drug mifepristone. Otherwise, the allegations of Paragraph 1 state

legal conclusions and require no response from Defendants. To the extent a response is required, the allegations are denied.

2. The allegations of Paragraph 2 state legal conclusions and require no response from Defendants. To the extent a response is required, the allegations are denied.

3. Defendants admit, on information and belief, that the FDA approved mifepristone for use under the trade name Mifeprex for the medical termination of intrauterine pregnancy, in a two-drug regimen with misoprostol. Defendants lack sufficient information and knowledge to form a belief as to what data the FDA reviewed or the agency's conclusions. Except as expressly admitted herein, Defendants deny the allegations of Paragraph 3.

4. The publication cited in Paragraph 4 speaks for itself and serves as the best evidence of its contents. To the extent that a response is deemed to be required, Defendants lack sufficient information and knowledge to form a belief as to the truth or falsity of the allegations of Paragraph 4.

5. Defendants admit, on information and belief, that the FDA has revised the Mifepristone REMS. Defendants further admit that the FDA, Single Shared System for mifepristone 2000 MG, Risk Evaluation and Mitigation Strategy, attached as Exhibit A to the First Amended Complaint, imposes requirements on healthcare providers who prescribe mifepristone. Exhibit A speaks for itself and serves as the best evidence of its contents. To the extent

that a response is deemed to be required, Defendants lack sufficient information and knowledge to form a belief as to the truth or falsity of the allegations of Paragraph 5.

6. Defendants admit that North Carolina has imposed laws and regulations relating to abortions, including those identified in the First Amended Complaint at N.C.G.S § 14-44, 14-45, 14-45.1, 90-21.82, 90-21.90, and N.C. Sess. Law 2023-14 ("S.L. 2023-14"). Those laws, regulations, and session law speak for themselves and serve as the best evidence of their contents. The remaining allegations of Paragraph 6 state legal conclusions and require no response from Defendants. To the extent a response is required, the allegations are denied.

7. Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 7.

8. Defendants admit that medical providers in North Carolina are subject to various state laws and regulations relating to the provision of abortion care. Those laws and regulations speak for themselves and serve as the best evidence of their requirements. To the extent a response is required, the allegations are denied.

9. Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of Plaintiff's allegations regarding the costs and burdens on her and her patients. Defendants

admit that the Licensee-Patient Relationship position statement states, in full, that "[p]atient advocacy is a fundamental element of the licensee-patient relationship and should not be altered by the health care system or setting in which a licensee practices." N.C. Med. Bd., Position Statements, *The Licensee-Patient Relationship* 2.1.1: (Mar. 2022) ("N.C. Med. Bd. Position Statement"). Defendants further admit that the Licensee-Patient Relationship position statement states that "[a]ll licensees should exercise their best professional judgement when making patient care decisions." Unless otherwise admitted, the writings and legal opinion cited in Paragraph 9 speak for themselves and serve as the best evidence of their contents. Except as expressly admitted herein, Defendants deny the allegations of Paragraph 9.

10. Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 10.

11. Defendants admit, on information and belief, that the FDA has revised the Mifepristone REMS. The Mifepristone REMS speaks for itself and serves as the best evidence of its contents. To the extent that a response to Paragraph 11 is deemed to be required, Defendants lack sufficient information and knowledge to form a belief as to the truth or falsity of the allegations of Paragraph 11.

12. The allegations of Paragraph 12 state legal conclusions and require no response from Defendants. To the extent a response is required, the allegations are denied.

13. Defendants admit that Plaintiff seeks a declaratory judgment as described in Paragraph 13.

14. Defendants admit, on information and belief, that Plaintiff, Dr. Amy Bryant, is a North Carolina board-certified and licensed physician with a medical practice in Orange County, North Carolina. Defendants further admit, on information and belief, that Plaintiff is certified to prescribe mifepristone. Except as expressly admitted herein, Defendants lack sufficient information and knowledge to form a belief as to the truth or falsity of the allegations of Paragraph 14.

15. Defendants admit that Joshua H. Stein is the Attorney General of North Carolina, and has been named as a defendant in this lawsuit in his official capacity. Defendants admit that the Attorney General is the chief law enforcement officer in the State with power to enforce State laws. The remaining allegations of Paragraph 15 state legal conclusions and require no response from Defendants. To the extent a response is required, the allegations are denied.

16. Defendants, on information and belief, admit the allegations of Paragraph 16.

17. Defendants, on information and belief, admit the allegations of Paragraph 17.

18. Admitted.

19. Admitted.

20. Admitted.

21. Admitted.

22. Admitted.

23. Admitted.

24. Admitted.

25. Admitted.

26. Admitted.

27. Admitted.

28. Admitted.

29. Admitted.

30. The allegations of Paragraph 30 state legal conclusions and require no response from Defendants.

31. The allegation of Paragraph 31 regarding personal jurisdiction states a legal conclusion and requires no response from Defendants. The answering Defendants admit that they are domiciled in North Carolina, that enactment of the laws at issue here occurred in North Carolina, and that enforcement of the laws at issue here would occur in North Carolina. The answering Defendants admit, on information and belief, that District

Attorney Jeff Nieman and Attorney General Stein are domiciled in North Carolina.

32. The allegation of Paragraph 32 regarding venue states a legal conclusion and requires no response from Defendants. Defendants admit, on information and belief, that Plaintiff practices medicine in this judicial district.

33. The allegations of Paragraph 33 state legal conclusions and require no response from Defendants. To the extent a response is required, the allegations are denied.

34. The allegation of Paragraph 34 regarding standing state a legal conclusion and requires no response from Defendants. Defendants admit that the Licensee-Patient Relationship position statement states that "[p]atient advocacy is a fundamental element of the licensee-patient relationship and should not be altered by the health care system or setting in which a licensee practices." N.C. Med. Bd., Position Statements, *The Licensee-Patient Relationship* 2.1.1: (Mar. 2022) ("N.C. Med. Bd. Position Statement"). Defendants further admit that the Licensee-Patient Relationship position statement states that "[a]ll licensees should exercise their best professional judgement when making patient care decisions." Unless otherwise admitted, the writings and legal opinion cited in Paragraph 34 speak for themselves and serve as the best evidence of their contents. Defendants admit that violation of the challenged statutory and regulatory

provisions may result in criminal, civil, and/or administrative sanctions. The challenged statutory and regulatory provisions speak for themselves and serve as the best evidence of their contents. Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of Paragraph 34.

35. The allegation of Paragraph 35 regarding ripeness states a legal conclusion and requires no response from Defendants. To the extent a response is required, the allegations are denied.

36. The allegations of Paragraph 36 state legal conclusions and require no response from Defendants. Moreover, the cited statutes speak for themselves and serve as the best evidence of their contents. To the extent a response is required, Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations.

37. The allegations of Paragraph 37 state legal conclusions and require no response from Defendants. Moreover, the Federal Food, Drug, and Cosmetic Act ("FDCA") speaks for itself and serves as the best evidence of its contents. To the extent a response is required, Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations.

38. The allegations of Paragraph 38 state legal conclusions and require no response from Defendants. Moreover, the cited statutes speak for themselves and serve as the best evidence of

their contents. To the extent a response is required, Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations.

39. The allegations of Paragraph 39 state legal conclusions and require no response from Defendants. Moreover, the cited legal opinion speaks for itself and serves as the best evidence of its contents. To the extent a response is required, Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations.

40. The allegations of Paragraph 40 state legal conclusions and require no response from Defendants. Moreover, the cited act and statutes speak for themselves and serve as the best evidence of their contents. To the extent a response is required, Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations.

41. The allegations of Paragraph 41 state legal conclusions and require no response from Defendants. Moreover, the cited statutes and REMS Assessment Draft Guidance document speak for themselves and serve as the best evidence of their contents. To the extent a response is required, Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations.

42. The allegations of Paragraph 42 state legal conclusions and require no response from Defendants. Moreover, the cited act

and statutes speak for themselves and serve as the best evidence of their contents. To the extent a response is required, Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations.

43. The allegations of Paragraph 43 state legal conclusions and require no response from Defendants. Moreover, the cited statutes speak for themselves and serve as the best evidence of their contents. To the extent a response is required, Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations.

44. The allegations of Paragraph 44 state legal conclusions and require no response from Defendants. Moreover, the cited statutes speak for themselves and serve as the best evidence of their contents. To the extent a response is required, Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations.

45. The allegations of Paragraph 45 state legal conclusions and require no response from Defendants. Moreover, the cited statute speaks for itself and serves as the best evidence of its contents. To the extent a response is required, Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations.

46. The allegations of Paragraph 46 state legal conclusions and require no response from Defendants. Moreover, the cited

statutes speak for themselves and serve as the best evidence of their contents. To the extent a response is required, Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations.

47. The allegations of Paragraph 47 state legal conclusions and require no response from Defendants. Moreover, the cited REMS Assessment Draft Guidance document speaks for itself and serves as the best evidence of its contents. To the extent a response is required, Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations.

48. The documents cited by Paragraph 48 speak for themselves and serve as the best evidence of their contents. To the extent a response is required, Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 48.

49. Defendants admit, on information and belief, that mifepristone is used in a two-drug regimen with misoprostol to terminate intrauterine pregnancies; and that patients typically take mifepristone first, which works by blocking progesterone, followed by misoprostol 24 to 48 hours later, which causes uterine contractions. The medical journal cited in Paragraph 49 speaks for itself and serves as the best evidence of its contents. To the extent a response is required, Defendants lack knowledge or

information sufficient to form a belief as to the truth or falsity of the allegations not already admitted in Paragraph 49.

50. Defendants admit, on information and belief, that the FDA approved mifepristone in 2000 under the trade name Mifeprex for the medical termination of intrauterine pregnancy, in a regimen with misoprostol; and that the FDA approved a generic version of mifepristone in 2019. Otherwise, the Mifeprex (mifepristone) Prescribing Information (2000) document, attached to the First Amended Complaint as Exhibit B, speaks for itself and serves as the best evidence of its contents.

51. Defendants admit, on information and belief, that the FDA has revised its regulatory controls for mifepristone and in doing so eliminated and/or modified certain requirements for the provision of mifepristone. The Mifepristone REMS, labeling, and risk mitigation plan referenced in Paragraph 51 speaks for itself and serves as the best evidence of its contents. To the extent a response is required, Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not already admitted in Paragraph 51.

52. Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 52.

53. The writings referenced in Paragraph 53 speak for themselves and serve as the best evidence of their contents. To

the extent a response is required, Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 53.

54. The statute and writing referenced in Paragraph 54 speak for themselves and serve as the best evidence of their contents. To the extent a response is required, Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 54.

55. The writings referenced in Paragraph 55 speak for themselves and serve as the best evidence of their contents. To the extent a response is required, Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 55.

56. The writing referenced in Paragraph 56 speaks for itself and serves as the best evidence of its contents. To the extent a response is required, Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 56.

57. The writings referenced in Paragraph 57 speak for themselves and serve as the best evidence of their contents. To the extent a response is required, Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 57.

58. Defendants admit, on information and belief, that a Prescriber Agreement Form and Patient Agreement Form remain part of the Mifepristone REMS, and that they have been modified since the initial approval of mifepristone. Otherwise, the writings referenced in Paragraph 58 speak for themselves and serve as the best evidence of their contents.

59. Defendants admit, on information and belief, that under the Food and Drug Administration Amendments Act of 2007 ("FDAAA"), mifepristone was deemed to have an approved REMS, and required the drug's sponsors to submit a proposed REMS for approval. Otherwise, the statutes and federal registry entry cited in Paragraph 59 speak for themselves and serve as the best evidence of their contents.

60. Defendants admit, on information and belief, that the FDA approved the first REMS for mifepristone in 2011. Otherwise, the writings cited in Paragraph 60 speak for themselves and serve as the best evidence of their contents.

61. The writings referenced in Paragraph 61 speak for themselves and serve as the best evidence of their contents. To the extent a response is required, Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 61.

62. Defendants admit, on information and belief, that the 2016 Mifepristone REMS authorized certified "healthcare providers" to prescribe mifepristone, whereas the 2011 Mifepristone REMS

authorized "physician[s]" to prescribe mifepristone. Otherwise, the writings cited in Paragraph 62 speak for themselves and serve as the best evidence of their contents.

63. The writings referenced in Paragraph 63 speak for themselves and serve as the best evidence of their contents. To the extent a response is required, Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 63.

64. The writing referenced in Paragraph 64 speaks for itself and serves as the best evidence of its contents. To the extent a response is required, Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 64.

65. The writings referenced in Paragraph 65 speak for themselves and serve as the best evidence of their contents. To the extent a response is required, Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 65.

66. The writings referenced in Paragraph 66 speak for themselves and serve as the best evidence of their contents. To the extent a response is required, Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 66.

67. The writings referenced in Paragraph 67 speak for themselves and serve as the best evidence of their contents. To the extent a response is required, Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 67.

68. The writings referenced in Paragraph 68 speak for themselves and serve as the best evidence of their contents. To the extent a response is required, Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 68.

69. Defendants admit, on information and belief, that in January 2023 the FDA approved a modification of the Mifepristone REMS; that the modification removed the requirement that mifepristone be dispensed in clinics, medical offices, and hospitals; and that the modification added a requirement for pharmacies dispensing mifepristone to verify prescriber certification. Otherwise, the writings cited in Paragraph 69 speak for themselves and serve as the best evidence of their contents. To the extent a response is required, Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 69 not specifically admitted to herein.

70. Defendants admit, on information and belief that the Mifepristone REMS requires certification of healthcare providers

prescribing mifepristone. Otherwise, the writings cited in Paragraph 70 speak for themselves and serve as the best evidence of their contents. To the extent a response is required, Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 70 not specifically admitted to herein.

71. Defendants admit, on information and belief that the 2023 Mifepristone REMS contains certification requirements from pharmacies that dispense mifepristone. Otherwise, the writings cited in Paragraph 71 speak for themselves and serve as the best evidence of their contents. To the extent a response is required, Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 71 not specifically admitted to herein.

72. The writing referenced in Paragraph 72 speaks for itself and serves as the best evidence of its contents. To the extent a response is required, Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 72.

73. Defendants admit, on information and belief, that the requirements listed in Paragraph 73 are among the requirements contained in the 2023 Mifepristone REMS. Otherwise, the 2023 Mifepristone REMS speaks for itself and serves as the best evidence of its contents.

74. The statute referenced in Paragraph 74 speaks for itself and serves as the best evidence of its contents. To the extent a response is required, Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 74.

75. The writings referenced in Paragraph 75 speak for themselves and serve as the best evidence of their contents. To the extent a response is required, Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 75.

76. The allegations of Paragraph 76 state legal conclusions and require no response from Defendants. To the extent a response is required, the allegations are denied.

77. Defendants admit that medical abortion is legal in North Carolina when performed in compliance with state law, including N.C.G.S. § 14-44, 14-45, 14-45.1, and S.L. 2023-14. Otherwise, the allegations of Paragraph 77 state legal conclusions and require no response from Defendants. To the extent a response is required, the allegations are denied.

78. Defendants admit that North Carolina law includes requirements that must be satisfied by physicians performing or inducing medical abortions, including a medical abortion with mifepristone. The statutes, regulations, and session law cited in Paragraph 78 speak for themselves and are the best evidence of

their contents. Otherwise, the allegations of Paragraph 78 state legal conclusions and require no response from Defendants. To the extent a response is required, the allegations are denied.

79. Defendants admit that North Carolina law includes requirements that must be satisfied before any abortion, including a medical abortion with mifepristone. The statutes, regulations, and session law cited in Paragraph 79 speak for themselves and are the best evidence of their contents. Otherwise, the allegations of Paragraph 79 state legal conclusions and require no response from Defendants. To the extent a response is required, the allegations are denied.

80. Defendants admit that North Carolina law includes reporting requirements for medical abortions, including a medical abortion with mifepristone. The statutes and session law cited in Paragraph 80 speak for themselves and are the best evidence of their contents. Otherwise, the allegations of Paragraph 80 state legal conclusions and require no response from Defendants. To the extent a response is required, the allegations are denied.

81. Defendants admit that a physician who "[p]roduce[s] or attempt[s] to produce an abortion contrary to law" may be subject to disciplinary action by the North Carolina Medical Board, including fines, and suspension or revocation of the physician's medical license. Defendants further admit that performing an abortion in violation of North Carolina law may result in criminal

sanctions. Otherwise, the allegations of Paragraph 81 state legal conclusions and require no response from Defendants. To the extent a response is required, the allegations are denied.

82. The allegations of Paragraph 82 state legal conclusions and require no response from Defendants. To the extent a response is required, Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations.

83. Defendants incorporate by reference and reassert their responses to Plaintiff's allegations in all of the Paragraphs of this Answer, as though set forth fully herein.

84. The allegations of Paragraph 84 state legal conclusions and require no response from Defendants. To the extent a response is required, the allegations are denied.

85. The allegations of Paragraph 85 state legal conclusions and require no response from Defendants. To the extent a response is required, the allegations are denied.

86. The allegations of Paragraph 86 state legal conclusions and require no response from Defendants. To the extent a response is required, the allegations are denied.

87. The allegations of Paragraph 87 state legal conclusions and require no response from Defendants. To the extent a response is required, the allegations are denied.

88. The allegations of Paragraph 88 state legal conclusions and require no response from Defendants. To the extent a response is required, the allegations are denied.

RESPONSE TO PLAINTIFF'S PRAYER FOR RELIEF

Paragraphs 1 through 4 of Plaintiff's "Prayer for Relief" constitute and/or characterize Plaintiff's request for relief in this action, and require no response from Defendants. To the extent a response is required, the allegations are denied.

FURTHER DEFENSES

Defendants plead and reserve the right to assert any further defenses that may become apparent during the course of this litigation and discovery.

Respectfully submitted, this 21st day of August 2023.

JOSHUA H. STEIN
Attorney General

/s/ Michael Bulleri
Michael Bulleri
Special Deputy Attorney
General
N.C. State Bar No. 35196
E-mail:
mbulleri@ncdoj.gov

N.C. Department of
Justice
P.O. Box 629
Raleigh, NC 27602-0629
Telephone: (919) 716-
6942
Facsimile: (919) 716-
6761